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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,715	01/22/2004	Kristian DiMatteo	10123/03601	5203
7590 Patrick J. Fay, Esq. FAY KAPLUN & MARCIN, LLP Suite 702 150 Broadway New York, NY 10038				
04/28/2009				
EXAMINER				
GRAY, PHILLIP A				
ART UNIT		PAPER NUMBER		
3767				
MAIL DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/762,715

**Applicant(s)**

DIMATTEO ET AL.

**Examiner**

Phillip Gray

**Art Unit**

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 3/6/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-19 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-19 and 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This office action is in response to applicant's communication of 3/6/2009. Currently claims 1-5, 7-19, and 21-24 are pending and stand rejected below. This office action has been reopened to make new rejections. The finality of the last action is withdrawn.

#### ***Response to Arguments***

Applicant's arguments filed 3/6/2009 have been fully considered but they are not persuasive. Applicant's argue that the added claim language of a bypass element "to introduce fluids into the catheter distally of" the valve, and an overpressure control element is not disclosed in the prior art of record. Examiner is maintaining the position below concerning the "overpressure control element" (see rejection below), and concerning the language of the newly amended claims it is examiners position that irrigation fluid (12) in Dryden would be introduced distally of the valve (23) or (35). The elements disclosed Dryden are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. See rejection discussion below.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-8, 11-13, 18-19, 21, and 23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dryden (U.S. Patent 5,125,893).

Dryden discloses a catheter system with a connector for injecting fluid to a catheter (as in figure 1) comprising an attachment portion (near 27) to fluidly couple to a source of pressurized fluid (12 for example), an elongate tubular hypotube bypass element (element 31/28) adapted to open a valve (such as 23) of the catheter (such as system 11/17/22) to permit fluid to flow into the catheter without impinging on the valve (as described in columns 2-3, wherein the tubular bypass element has a diameter to fit in a flow opening of the valve) and an over pressure control element (35 or 36) which would be fully capable of being adapted to maintain a pressure of fluid within the connector below a predetermined threshold (as described in column 2 lines 45-56) and be a pressure relief valve. It is examiners position that an overpressure control element or "pressure relief valve" (as identified in applicant's claim 7) adapted to maintain a pressure of fluid within the connector below a predetermined threshold level is inherent in the Dryden reference (valve 35 i.e. and its function) but in the alternative it would have been an obvious modification thereof and well known to a person having ordinary

skill in the art to construct the valve (35) to be an "over pressure control element" to allow a safe pressure level of fluid to reach a patient, and be a pressure relief valve. Such valves are well known in the art. For some information on possible over pressure valve types and teachings as to the benefits see Binard et al. (U.S. Patent 4,124,525 and paragraphs at columns 1-2 and column 4 lines 53-65 for examples). These types of pressure relief valves have controlled failure elements designed to fail when a fluid pressure level reached a threshold. It is examiners position that the bypass element is fully capable of being adapted to open a pressure actuated safety valve of a venous catheter, and that the attachment portion is fully capable of being adapted to connect to a contrast media power injection system. It has been held that the recitation that an element is "adapted to" to perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. The elements disclosed in Dryden are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-10, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dryden in view of Campbell et al. (U.S. Patent Number 6,375,637).

Dryden discloses the claimed invention except for the overpressure control element being an extension tube and having a external collection jacket disposed around. Campbell teaches that it is known to use an overpressure control element being an extension tube and having a external collection jacket (Campbell 31) disposed around as set forth in paragraphs at columns 1-3 to provide a controlling means to prevent catastrophic failure of the device by controlling the pressure inside the catheter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Dryden with an overpressure control element being an extension tube and having a external collection jacket disposed around as taught by Campbell, since such a modification would provide the system with the overpressure control element extension tube and an external collection

jacket for providing a controlling means to prevent catastrophic failure of the device by controlling the pressure inside the catheter.

Claims 14 –17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dryden.

Dryden discloses the claimed invention except for the threshold level being approximately 300, 100, 80, or 40 p.s.i.. It would have been obvious to one having ordinary skill in the art at the time the invention was made for the threshold level to be approximately 300, 100, 80, or 40 p.s.i., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955), and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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/Kevin C. Simons/

Supervisory Patent Examiner, Art Unit 3767